

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): TURPEN, et al.

Serial No.: 10/602,219

Filed: 6/23/2003

Title: Production of Lysosomal Enzymes in  
Plants by Transient Expression

Attorney Docket No.: LSBC-0087-CN09B

Group Art Unit: 1652

Examiner: RAMIREZ, Delia M.

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

This Information Disclosure Statement is submitted under 37 CFR 1.97(b) (before mailing date of first office action on the merits).

Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

I hereby certify that this Correspondence is being deposited with the United States Postal service with sufficient postage for first class mail in an envelope address to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: 18 Sept 2004

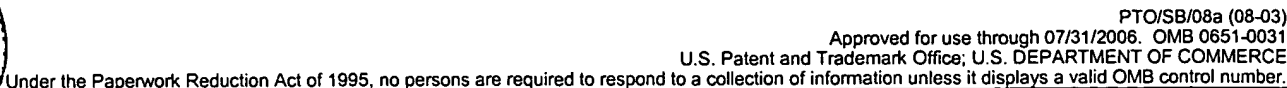
Thomas Gallegos  
Thomas Gallegos, Reg. No. 32,692

Respectfully submitted,

Thomas Gallegos  
Thomas Gallegos, Reg. No. 32,692  
Attorney for Applicant(s)  
Large Scale Biology Corporation

Date: 18 Sept 2004

Telephone No.: (707) 469-2307

**Complete if Known**

Application Number	10/602,219
Filing Date	6/23/2003
First Named Inventor	TURPEN et al.
Art Unit	1652
Examiner Name	RAMIREZ, Delia M.
Attorney Docket Number	LSBC-0087-CN09B

Sheet	1	of	5
-------	---	----	---

[illegible]

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/602,219
				Filing Date	6/23/2003
				First Named Inventor	TURPEN, et al.
				Group Art Unit	1652
				Examiner Name	RAMIREZ, Delia M.
Sheet	2	of	5	Attorney Docket Number	LSBC-0087-CN09B

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	r <sup>2</sup>
		BORK, "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle", <i>Genome Research</i> (2000) 10:398-400	
		BOWIE, et al., "Diciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions", <i>Science</i> (1990) 247:1306-1310	
		BRADY, "Fabry Disease", <i>Peripheral Neropathym</i> , 3 <sup>rd</sup> ed., 1169-1178 (1993), W.B. Saunders	
		BROUN, et al., "Catalytic plasticity of fatty acid modification enzymes underlying chemical diversity of plant lipids", <i>Science</i> (1998) 282:1315-1317	
		CHAPMAN, et al., "Potato virus X as a vector for gene expression in plants", <i>The Plant Journal</i> (1992) 2(4):549-557	
		COPPOLA, et al., "Characterization of glycosylated and catalytically active recombinant human $\alpha$ -galactosidase A using a baculovirus vector", <i>Gene</i> (1994) 144:197-203	
		CRAMER, <i>American Journal of Human Genetics</i> , (1995) 57(4), published for the Amercian of Human Genetic by the University of Chicago Press	
		DESNICK, et al., " $\alpha$ -Galactosidase A Deficiency: Fabry Disease", <i>The Metabolic Bases of Inherited Diseases</i> , Chapter 89, pp. 2741-2784 (1995), McGraw-Hill	
		ERICKSON, et al., "BioSynthesis of the Lysosomal Enzyme Glucocerebrosidase", <i>J. Bio. Chem.</i> , (1985) 260(26):14319-14324	
		FERRARI, et al., "Cloning and expression of a soluble sialidase from Chinese hamster ovary cells: sequence alignment similarities to bacterial sialidases", <i>Glycobiology</i> , (1994) 4(3):367-373	
		FRANK, et al., "Automation of DNA Sequencing Reactions and Related Techniques: A Workstation for Micromanipulation of Liquids", <i>Biotechnology</i> , (1988) 6:1211	
		FURBISH, et al., "Enzyme replacement therapy in Gaucher's disease: Large-scale purification of glucocerebrosidase suitable for human administration", <i>Proc. Natl. Acad. Sci.</i> , (1977) 71(8):3560-3563	
		FURBISH, et al., "Uptake and Distribution of Placental Glucocerebrosidase in at Hepatic Cells and Effects of Sequential Deglycosylation", <i>Biochemica et biophysica Acta.</i> , (1981) 673:425-434	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/602,219		
		Filing Date	6/23/2003		
		First Named Inventor	TURPEN et al.		
		Group Art Unit	1652		
		Examiner Name	RAMIREZ, Delia M.		
Sheet	3	of	5	Attorney Docket Number	LSBC-0087-CN09B

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		GRABOWSKI, et al., "Expression of Functional Human Acid $\beta$ -glucosidase in COS-1 and <i>Sporodoptera frugiperda</i> Cells", <i>Enzyme</i> , (1989) 41:131-142	
		GRACE, et al., "Analyses of catalytic activity and inhibitor binding of human acid $\beta$ -glucosidase by site-directed mutagenesis", <i>J. Bio. Chem.</i> (1990) 265:6827-6835	
		GRACE, et al., "Analysis of Human Acid $\beta$ -glucosidase by Cite-Directed Mutagenesis and Heterologous Expression", <i>J. Bio. Chem.</i> (1994) 269(3): 2283-2291	
		GRACE and GRABOWSKI, "Human Acid $\beta$ -glucosidase: Glycosylation Is Required for Catalytic Activity", <i>Biochemical and Biophysical Research Communications</i> , (1990) 168(2):771-777	
		HASKINS, et al., "Alpha-L-Iduronidase Deficiency in a Cat: A Model Mucopolysaccharidosis I", <i>Pediat. Res.</i> (1979) 13:1294-1297	
		HOPP, et al., "A Short Polypeptide mark sequence useful for recombinant protein identification and purification", <i>Biotechnology</i> , (1988) 6:1204-1210	
		JONSSON, et al., "Biosynthesis and maturation of glucocerebrosidase in Gaucher fibroblasts", <i>Eur. J. Biochem.</i> , (1987) 164:171-179	
		KAPLAN, et al., "Phosphohexosyl components of a lysosomal enzyme are recognized by pinocytosis receptors on human fibroblasts", <i>Proc. Natl. Acad. Sci. USA</i> (1977) 74(5):2026-2030	
		KENWARD, et al., "Accumulation of Type I Fish Antifreeze Protein in Transgenic Tobacco Is Cold Specific", <i>Plant Mol. Biol.</i> (1993) 23:377-385	
		KORNFELD and MELLMAN, "The Biogenesis of Lysosomes", <i>Annu. Rev. Cell Biol.</i> , (1989) 5:483-525	
		LEE and RAIKHEL, "Prohevein is poorly processed but shows enhanced resistance to a chitin-binding fungus in transgenic tomato plants", <i>Brazilian J. Med. and Biol. Res.</i> , (1995) 28:743-750	
		MIYAMURA, et al., "A Carboxy-terminal Truncation of Human $\alpha$ -Galactosidase A in a Heterozygous Female with Fabry Disease and Modification of the Enzymatic Activity by the Carboxy-terminal Domain", <i>J. Clin. Invest.</i> , (1996) 98(8):1809-1817	
		MURRAY, et al., "Production of Recombinant Human Glucocerebrosidase in Plants", <i>Fed. of American Soc. for Experimental Biology</i> , (1996) 10(6):a1126	
		PARK, et al., "Structure and nucleotide sequence of tomato HMG2 encoding 3-hydroxy-3-methyl-glutaryl coenzyme A reductase", <i>Plant Mol. Biol.</i> (1992) 20:327-331	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/602,219		
		Filing Date	6/23/2003		
		First Named Inventor	TURPEN et al.		
		Group Art Unit	1652		
		Examiner Name	RAMIREZ, Delia M.		
Sheet	4	of	5	Attorney Docket Number	LSBC-0087-CN09B

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		SCHATZLE, et al., "Molecular Cloning and Characterization of the Structural Gene Coding for the Developmentally Regulated Lysosomal Enzyme, $\alpha$ -Mannosidase, in <i>Dictyostelium discoideum</i> , <i>J. Bio. Chem.</i> (1991) 267(6):4000-4007	
		SCHULZ and SCHIRMER, "Principles of Protein Structure", (1979) pp. 14-16, Springer-Verlag, eds.	
		SCOTT, et al., "Structure and Sequence of the Human $\alpha$ -L-Iduronidase Gene", <i>Genomics</i> , (1992) 13:1311-1313	
		SCOTT, et al., "Human $\alpha$ -L-iduronidase: cDNA isolation and expression", <i>Proc. Natl. Acad. Sci. USA</i> , (1991) 88:9695-9699	
		SEFFERNICK, et al., "Melamine Deaminase and Atrazine Chlorohydrolase: 98 percent Identical but Functionally Different", <i>J. Bacteriol.</i> (2001) 183(8):2405-2410	
		SHULL, et al., "Enzyme replacement in a canine model for Hurler syndrome", <i>Proc. Natl. Acad. Sci. USA</i> , (1994) 91:12937-12941	
		SIJMONS, et al., "Production of Correctly Processed Human Serum Albumin Transgenic Plants", <i>Biotechnology</i> , (1990) 8:217-221	
		SORGE, et al., "Molecular cloning and nucleotide sequence of human glucocerebrosidase cDNA", <i>Proc. Natl. Acad. Sci. USA</i> , (1985) 82:7289-7293	
		TAKAMATSU, et al., "Expression of bacterial chloramphenicol acetyltransferase gene in tobacco plants mediated by TMV-RNA", <i>EMBO J.</i> , (1987) 6(2):307-311	
		THORNBURG, et al., "Wound-inducible expression of a potato inhibitor II-chloramphenicol acetyltransferase gene fusion in transgenic tobacco plants", <i>Proc. Natl. Acad. Sci.</i> (1987) 84:744-748	
		TSUJI, et al., "Nucleotide Sequence of cDNA Containing the Complete Coding Sequence for Human Lysosomal Glucocerebrosidase", <i>J. Bio. Chem.</i> (1986) 261(1):50-53	
		VANDEKERCKHOVE, et al., "Enkephalins Produced in Transgenic Plants Using Modified 2S Seed Storage Proteins", <i>Biotechnology</i> , (1989) 7:929-933	
		VIERSTRA, "Protein Degradation in Plants", <i>Annual Review of Plant Physiology and Plant Molecular Biology</i> (1993) 44:385-410, Annual Reviews, Inc., Palo Alto, California	
		VON FIGURA and HASILIK, "Lysosomal Enzymes and Their Receptors", <i>Ann. Rev. Biochem.</i> , (1986) 55:167-193	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/602,219		
		Filing Date	6/23/2003		
		First Named Inventor	TURPEN et al.		
		Group Art Unit	1652		
		Examiner Name	RAMIREZ, Delia M.		
Sheet	5	of	5	Attorney Docket Number	LSBC-0087-CN09B

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	r <sup>2</sup>
		WARNER, et al., "Photolabeling of the $\alpha$ -Neuraminidase/ $\beta$ -Galactosidase Complex from Human Placenta with a Photoreactive Neuraminidase Inhibitor", <i>Biochem. and Biophys. Res. Comm.</i> (1990) 173(1):13-19	
		WEISSENBORN, "HMG-CoA reductase and terpenoid phytoalexins: Molecular specialization within a complex pathway", <i>Physiologia Plantarum</i> , (1995) 93:393-400	
		WELLS, "Additivity of Mutational Effects in Proteins", <i>Biochemistry</i> (1990) 29(37):8509-8517	
		WITKOWSKI, et al., "Conversion of a beta-Ketoacyl synthase to a malonyl decarboxylase by replacement of the active-site cysteine with glutamine", <i>Biochemistry</i> (1999) 38:11643-11650	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.